K092630

510(k) SUMMARY

OCT 22 2009

Submitter:

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US Agent:

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Official Correspondent:

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Device Identification

Proprietary Name: ZIROX

Common/Usual Name: Porcelain Powder

Classification Name: Porcelain Powder for Clinical Use

Product Code: EIH

Review Panel: Dental

Regulation Number: 872.6660

Substantially Equivalent Predicate Legally Marketed Devices

The subject device is deemed to be substantially equivalent to those following devices manufactured and currently available in commercial distribution.

Device Name	**Dentsply-Cercon Base**	**3M-LAVA Zirconia**	**Sagemax Bioceramics-Sagemax Z-Blank**
510(k) Number	K013230	K011394	K062695
Decision Date	10/25/2001	06/29/2001	10/20/2006
Decision	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Product Code	EIH	EIH	EIH
Regulation Number	872.6660	872.6660	872.6660

Device Description

ZIROX is a pre-formed machineable dental blank composed of zirconium oxide. ZIROX is available in partially-sintered. ZIROX is available in different shapes, and dimensions. ZIROX has two types that are 51x23x16 and 51x23x18. The only difference between 51x23x16 and 51x23x18 is the size(height).

ZIROX is a pre-formed ceramic dental blank intended for CAD/CAM fabrication of zirconia frameworks for all-ceramic dental restorations. ZIROX is designed for manufacturing ceramic dental restorations such as single crowns or bridgeworks. The blank is machined by the customers/dental laboratories on their milling centers or similar equipment using CAD/CAM techniques for design.

Indications for Use

The ZIROX is intended for CAD/CAM fabrication of all-ceramic dental restorations. The ZIROX is used for the manufacturing of inlays, onlays, veneers, crowns and bridges.

Technological Characteristics and Substantial Equivalence

ZIROX and predicate devices are identical in intended use and material. Therewith, ZIROX and predicate devices are biocompatible and have similar biomechanical strength and properties.

Based on the discussion above, ZENCERA, INC. believes that ZIROX is substantially equivalent in comparison with predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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REPUBLIC OF KOREA

OCT 22 2009

Re: K092630
Trade/Device Name: ZIROX
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
7Regulatory Class: II
Product Code: EIH
Dated: August 13, 2009
Received: August 27, 2009

Dear Mr. Hyun:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092630

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Prescription Use ___√___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulloy for KCR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092630